dynamic performances that we reported in our study and that were also confirmed by other authors.[3] This is quite unusual because, as the authors also state in their article, the in vitro effective orifice areas usually tend to overestimate the in vivo effective orifice areas. Furthermore, hemodynamic performances reported by Gerosa and coauthors do not reflect the in vitro hemodynamic performances reported for the CE Perimount standard valve by Marquez, Hon, and Yoganathan,[4] even though, as we already stressed, the valve itself is not changed.

In conclusion we agree with the authors that in vivo hemodynamic behavior of a valve might differ from our idealized assumption. However, we do believe that in the case of prostheses with a supra-annular design, such as the CE Perimount Magna, in vivo performances could be improved owing to the improved annulus-prosthesis interaction. In vitro tests, like those reported in this study, are extremely useful in evaluating opening mechanism as well as descriptive parameters for each prosthesis. However, a real comparison of hemodynamic performances of two valves with such a different design as the Mitroflow and CE Perimount Magna can be made only in a randomized study evaluating cumulative mean postoperative effective orifice areas for two groups.

Pasquale Totaro
Vincenzo Argano
Cardiac Surgery Division
Morriston Hospital
Swansea, United Kingdom

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Reply to the Editor:

We appreciate the comments of Drs Totaro and Argano on our recent article reporting in vitro performances of 5 different aortic tissue valves designed for supra-annular implantation.[1] To our minds, Drs Totaro and Argano raised more questions than comments, and we will discuss them in this reply.

Supra-annular concept. During aortic valve surgery, one of the main end points should logically be to relieve as much stenosis as possible by ensuring that the indexed effective orifice area (EOA) after the operation is above 0.85 to 0.90 cm^2/m^2.[2] Hence, it seems logical to implant supra-annular valves that are placed on top of the aortic annulus.[3] The Medtronic Mosaic, Carpentier-Edwards Magna, Sorin Soprano, SJM-Biocor-Epic-Supra, and Mitroflow valves all belong to this category of prostheses. The concept of supra-annular design is exclusively related to the placement of a specifically designed prosthesis, whether mechanical or biological, on the top of the aortic annulus. The patient annulus-prosthesis stent interaction may explain why different valves are more easily implanted than others, such as the Sorin Soprano[4] and the Mitroflow valves, which have a flat profile. However, it cannot explain differential hydraulic performances. Unfortunately, at present, the hypothetical differential hydraulic behavior between different prosthetic heart valves has not yet been sufficiently and comprehensively revealed.

The mounting ring of the pulse duplicator may have influenced the results. We tested production quality bioprostheses including the sewing ring cuffs secured in between the 2 O-rings of the pulse duplicator holder. To allow a meaningful comparison regardless industry-labeled valve size, we tested the supra-annular tissue valves with a tissue annulus diameter that could be fit in a 21-mm pulse duplicator ring. Owing to the supra-annular configuration, the opposite ring to fix the valve measured a size larger than the first (23 mm), therefore mimicking patient annulus-prosthesis interaction. The valves and the holder were sealed before testing. We agree with Drs Totaro and Argano that the pulse duplicator holder has a flat profile. Nevertheless, we selected a relatively homogeneous group of valves by using those with the largest tissue annulus diameter that could be superimposed in a definite pulse duplicator ring, without forcing the insertion, to avoid stent modification. We are fully aware that the distortion of the normal planar geometry of the pericardial prosthesis, induced by fixation with a second inadequate ring, may result in failure of adequate central leaflet coaptation. This was not the case in our study. Unfortunately, Totaro and Argano failed to constructively and fully explain how the mounting ring of the pulse duplicator may influence the comparison of different tissue valves analyzed under identical conditions.

Our in vitro hydrodynamic performances do not reflect the in vivo results reported by Totaro and associates.[5] The EOA, the most commonly used parameter for prosthetic heart valve comparison, is usually calculated by dividing the flow measured in the left ventricular outflow tract by transvalvular velocity. Meanwhile, whereas the EOA was initially believed to be a flow-independent parameter, Kadem and coauthors[6] recently suggested that it is actually a flow-related parameter. Therefore, the predominance of unsteady effects at low flow rates may be further considered in measuring prosthetic EOA.[6] Moreover, as recommended by the American Society of Echocardiography,[7] measurements should be made over 3 cycles in sinus rhythm or over 6 cycles in atrial fibrillation. It is further suggested that regurgitant jets also be calculated. These should be localized and then graded by a combination of the diameter of the base of the jet and the density and slope of the aortic regurgitant signal. Additionally, focusing on prosthetic heart valve comparison, the in vivo values should ideally be measured 1 year after the operation, because the latter may change during the first postoperative year.[2] Concerning the pressure recovery phenomenon, it has been shown that mild stenosis, such as in a patient with a prosthesis, and a small aortic root may lead to confounding echocardiographic results.[8] Pibarot and Dumesnil[2] also observed that the impact of a mismatch may be overestimated in these patients; thus, under the same indexed EOA, patients with a smaller aorta will have less energy loss and less burden on their left ventricle than those with a larger aorta.

To summarize, unfortunately, in vivo studies are not only limited by echocardiographic technical pitfalls, but also different clinical setting may intervene, leading to

misleading examinations, such as aortic root dimension and compliance,[9] systemic arterial pressure,[10,11] angiotensin-converting enzyme inhibitors assumption effect,[12] heart rate effect,[8] and surgeon-related confounding factors.[4,13]

A contemporaneous, prospective, nonrandomized study has been published by Botzenhardt and associates[3] and was referenced by Drs Totaro and Argano in their letter. Botzenhardt and coauthors,[3] by comparing supra-annular tissue valves of different types, concluded that the Carpentier-Edwards Magna valve is "the gold standard" in the panorama of supra-annular tissue valves. Moderate and severe mismatches were observed in 8.7% in the Magna group, 41.5% in the Perimount group, 40% in the Mosaic group, and 50% in the Soprano group.[3] The patients were comparable regarding preoperative and operative data, including number of patients, sex, age, body surface area, cardiac rhythm, New York Heart Association functional class, left ventricular mass index, valve size, and concomitant procedures. Unfortunately, in this nonrandomized study, the patients were not compared according to the stroke volume, as previously advised by the same authors[14]; moreover, the patients were followed up within 10 days postoperatively by transthoracic echocardiography, contrary to the previous echocardiographic recommendations.[7] Finally, the study results are based on 48 patients with a Perimount, 35 patients a Magna, 42 with a Mosaic, and only 16 with a Soprano valve, although the patients were more numerous than in Totaro and associates' study.[5]

In conclusion, unfortunately, both of these in vivo studies on aortic tissue valves, to a greater or lesser degree, miss the point. Although the timing of the echocardiographic analysis in the Totaro paper is one area criticized by Dr Kon and is cited as a limitation of the study,[5] the authors published the article with a title that makes it seem like a lure for larks. Furthermore, the data discussed in the Totaro article[5] are not the results of a "size by size analysis" between patients owing to the poor consistency of the cohort. Additionally, none of the papers previously discussed[3,5] focused on the diastolic phase of the cardiac cycle, and everyone ignored prosthesis regurgitation. In none of these studies was either the pressure recovery phenomenon or the aortic root dimension mentioned. Finally, besides all the limitations related to the echocardiographic measurements, in neither article was the systemic pressure or the effect of angiotensin-converting enzyme inhibitors considered. Maybe all these considerations explain why our in vitro results did not respect in vivo hemodynamic prosthetic performance.

Hydrodynamic performances reported by Gerosa and associates[1] do not reflect in vitro performances reported by Marquez, Hon, and Yoganathan.[15] Some authors observed that in vitro and in vivo measurements were comparable, although the in vitro usually overestimate in vivo values by 10% to 15%.[16,17] We did not make that observation.[1] That is one of the main future objectives of our studies. Worldwide, it is commonly maintained that the actual size and valve dimensions vary considerably from the labeled manufacturers' diameters and, furthermore, the labeled size is unrelated to any hemodynamically significant dimension.[2,13] Our recent findings[1] parallel those of previous authors,[18] since in all the measured valves there was evidence that the actual size and valve dimensions vary considerably from the labeled diameters. As a matter of fact, a comparison between Marquez, Hon, and Yoganathan[15] and our data is meaningless, because all test data presented in the former study were obtained at the Edwards Lifesciences LLC Product Evaluation Laboratory in Irvine (formerly a division of Baxter Healthcare, Inc). Additionally, in the Marquez study[15] the prostheses were mounted on a rubber aortic root annulus, making their results not comparable with ours.[1] The in vitro system that we have used has a virtually rigid arrangement section downstream from the aortic valve, which represents perhaps the single largest distortion from reality. Attaching a small compliant device to the downstream section could yield a significantly different system performance, mimicking an in vivo setting such as an aortic setting. However, if we compared two heart valves in this modified system, we would expect to appreciate the same differences between the two different valves. Therefore, the pulse duplicator device is not really designed to give an accurate representation of the true anatomy; instead, it is a system that provides an extraordinary and unquestionable bench test for comparison of different prostheses. Indeed, pericardial valve prostheses tested in our study[1] exhibited the smallest transprosthetic mean and peak gradients and the lowest stroke work loss in comparison with porcine valves, such as previously observed.[19] However, we could not observe significant hydrodynamic differences between the pericardial prostheses, although at increasing cardiac outputs (7 L/min) the Mitroflow valve performed significantly better.

Conclusions. The fundamental point is this: We are more interested in the hemodynamic performance that a patient with an aortic annulus of 20 mm can expect after aortic valve replacement with a given prosthesis. This is a very good point raised by Eichinger's group.[14]

Unfortunately, in vivo studies comparing different prostheses are difficult and, although randomized and well conducted, they are misleading. Several confounding factors, previously discussed, are frequently present, and they may confound the data obtained by echocardiographic studies. On the contrary, all these unforeseeable factors may be checked and added or removed at will during in vitro testing. For these reasons, we maintain that it is hazardous to conclude that a prosthesis model is the gold standard by interpreting only clinical results.

In conclusion, the most striking finding of an in vitro study is the ability to obtain a unique hydrodynamic comparison of different models of supra-annular tissue valves fitting a specified artificial aortic annulus, regardless of the size indicated by the manufacturer's label.

Gino Gerosa, MD[a]
Vincenzo Tarzia, MD[a]
Giulio Rizzoli, MD[a]
Tomaso Bottio, MD, PhD[b]
Cardiovascular Institute
University of Padova
Padua, Italy[a]
Cardiovascular Institute
University of Brescia
Brescia, Italy[b]

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Papillary fibroelastoma of aortic valve: Early diagnosis and surgical management

To the Editor:

We read with great interest the article by Vagefi and associates[1] regarding their experience with papillary fibroelastoma of the aortic valve. We had a similar experience with 2 patients having very small papillary fibroelastomas who were referred to us and had their tumors excised urgently.

A 68-year-old woman presented to her general practitioner with a 3-month history of symptoms including one transient ischemic attack (TIA).[2] The patient subsequently underwent echocardiography, which demonstrated a mobile mass attached by a thin stalk to the aortic valve. A 15-mm long and 2 mm in diameter tumor attached to the noncoronary cusp of the aortic valve was resected with standard cardiopulmonary bypass.

A 67-year-old man was referred with a recent history of multiple TIAs. Various investigations including carotid Doppler and transthoracic echocardiogram were inconclusive. However transesophageal echocardiography (TEE) revealed a 5 × 1-mm pedunculated tumor attached to the aortic valve. At the time of surgery, a small tumor with a thin stalk was found attached to the undersurface of the left coronary cusp (Figure 1). Both patients had an uncomplicated recovery and were discharged home on day 5.

Our patients were very similar to the case reported by Vagefi and colleagues in that both had an early diagnosis of the tumor made by echocardiography on the basis of neurologic symptoms. Both of our patients had their tumors shaved off the structurally normal aortic valve on an urgent basis. At the conclusion of the procedure, intraoperative TEE demonstrated a competent aortic valve with no evidence of residual tumor or aortic insufficiency.

It seems that an early diagnosis of these tumors is being made with very small masses detected with echocardiography. We emphasize the importance of prompt excision of these tumors owing to the risk of preoperative thromboembolic phenomena.[3]

Pankaj Saxena, MCh, DNB
Igor E. Konstantinov, MD, PhD
Andrew Lee, MBBS
Mark A. J. Newman, FRACS
Department of Cardiothoracic Surgery
Sir Charles Gairdner Hospital
Nedlands, WA, Australia

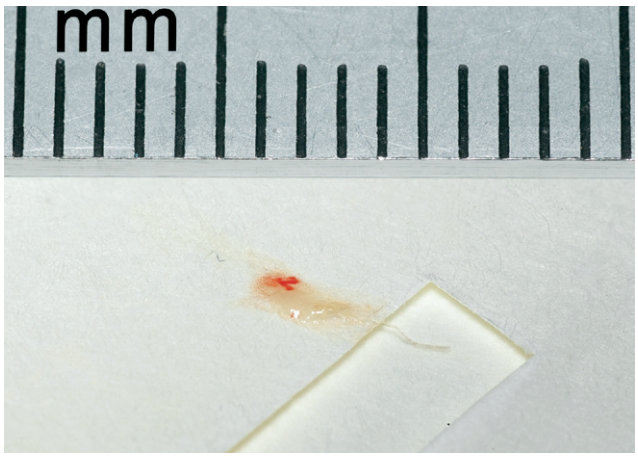

Figure 1. Papillary fibroelastoma excised from aortic valve of patient 2.